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April 29, 2021

VIA ECF

Honorable Madeline Cox Arleo, U.S.D.J.
United States District Court
Martin Luther King, Jr. Federal
Building & Courthouse
50 Walnut Street
Newark, New Jersey 07102

Re: *Pacira BioSciences, Inc. v. American Society of Anesthesiologists, Inc., et al.*
Case No. 21-cv-9264-MCA-JSA

Dear Judge Arleo:

Defendants respectfully submit this letter memorandum in support of their motion for a case management conference at which the Court will set an appropriate schedule for discovery, briefing, and an evidentiary hearing on Plaintiff, Pacira BioSciences, Inc.'s ("Pacira"), pending motion for a preliminary injunction. That motion, which is presently returnable May 17, 2021, asks the Court to force Defendant American Society of Anesthesiologists ("ASA") to "de-publish" two research papers and an editorial that appeared in the February 2021 issue of its Anesthesiology journal, widely regarded as the country's leading scientific journal in the field. Those three works were authored by the individual Defendants, 11 preeminent doctors.

Pacira did not initiate these proceedings by Order to Show Cause, instead filing its preliminary injunction motion together with its Complaint on April 14, 2021. (ECF #3). As a result, its motion was given an automatic return date of May 17, 2021. Before seeking this Court's intervention, Defendants asked Pacira to adjourn its motion for six weeks to allow Defendants to take expedited discovery, file opposition to, and prepare for a hearing on that motion. Although Pacira spent more than three months drafting its brief and gathering evidentiary submissions in support of its motion—from December 2020, when the papers first became available on the ASA website, until April 14, 2021, when it filed this action—Pacira declined that request. Accordingly, Defendants now ask your Honor to convene a case management conference and thereafter set the discovery, briefing and hearing schedule proposed below.

Pacira's Complaint purports to state a claim for trade libel. But this is not the typical trade libel claim, in which one competitor disputes what another competitor is telling the marketplace about its products. Rather, Pacira is suing over the content of scientific papers written by leading researchers in the field, which were anonymously peer-reviewed before being published. The papers concern Pacira's controversial prescription pain medication liposomal bupivacaine, which

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it sells under the tradename Exparel. One paper reviewed the results of clinical trials (and is thus deemed a “meta-analysis”). Another reported the results of a recent clinical trial. And the editorial expressed opinions about the FDA drug approval process and Pacira’s efficacy claims in light of the existing literature.

Defendants stand behind these three works and the integrity and scholarship of all who contributed to them. The authors are leading physicians and researchers in the fields of anesthesiology and clinical studies, have published hundreds of peer-reviewed articles in medical and scientific journals, and include:

- Evan D. Kharasch, M.D., Ph.D., Editor-in-Chief Anesthesiology, Professor of Anesthesiology and Vice-Chair for Innovation, Department of Anesthesiology, and Director of Research Entrepreneurship, Duke University School of Medicine; member of the Institute of Medicine of the National Academy of Sciences;
- Mary Ellen McCann, M.D., Ph.D., Associate Professor of Anesthesia at Harvard Medical School; Senior Associate in Perioperative Anesthesia, Department of Anesthesiology, Critical Care and Pain Medicine at Children’s Hospital of Boston; member of the FDA’s Anesthetic and Analgesic Drug Products Advisory Committee;
- Brian Ilfeld, M.D., Ph.D., Professor In Residence, Anesthesiology, University of California at San Diego, School of Medicine, primary investigator on 57 peer-reviewed publications, 35 of which were randomized clinical trials;
- Richard Brull, M.D., FRCPC, Professor of Anesthesia at the University of Toronto, and Chair in Ambulatory Anesthesia and Women’s Health at Women’s College Hospital in Toronto, Ontario;
- James C. Eisenach, M.D., Professor of Anesthesiology and Physiology & Pharmacology, Wake Forest University School of Medicine. Elected member of the National Academy of Medicine. President of the Foundation for Anesthesia Education and Research;
- Rodney A. Gabriel, M.D., Assistant Clinical Professor of Anesthesiology and Associate Adjunct Professor in Biomedical Informatics at the University of California, San Diego. Chief of the Division of Regional Anesthesia and Acute Pain Medicine and Medical Director at the Koman Family Outpatient Pavilion Surgery Center, University of California, San Diego;
- Faraj Abdallah M.D., MS(c), Associate Professor of Anesthesiology and Pain Medicine, University of Toronto, Department of Anesthesiology and Pain Medicine, The Ottawa Hospital;

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- Michael Essandoh, M.D., Anesthesiologist and Associate Director of Anesthesiology Clinical Research, Wexner Medical Center, Ohio State University;
- Nasir Hussain, M.D., M.Sc., Anesthesiology Resident at Ohio State University College of Medicine and co-author of numerous peer-reviewed papers concerning bupivacaine and other pain medications;
- Tristan Weaver, M.D., Board Certified Anesthesiologist, Wexner Medical Center, Ohio State University.

Given the reputational harm to Defendants from Pacira's scurrilous allegations, which it has widely disseminated, Defendants share Pacira's asserted interest in resolving its preliminary injunction motion on the merits as soon as possible. But the motion raises numerous fact and legal issues that Defendants must address, including the following:

1. Defendants assert that the two research papers and editorial constitute scientific opinion not subject to a trade libel claim.
2. Defendants dispute that the works' methodologies and conclusions are "false."
3. Defendants dispute that Pacira has established malice, *i.e.*, that the authors made statements of fact that they knew to be false or for which they entertained serious doubts about their truthfulness.
4. Defendants dispute that the research papers or the editorial could have caused any reputational harm to Pacira or Exparel, even if actionable, given that: (a) an avalanche of prior studies have found Exparel to provide no clinical benefit when compared to regular bupivacaine or other non-opioid local anesthetics, (b) Pacira has been the subject of shareholder litigation over management's statements and conduct, and (c) Pacira paid millions of dollars last year to settle an Exparel-related False Claims Act case (that the Department of Justice itself chose to prosecute) involving "kick-backs" Pacira paid to get doctors to prescribe the drug.
5. There is no benefit from "de-publishing" content from Defendant ASA's website that has been available on websites around the world since late December 2020.
6. Such a post-publication restraint is not lawful.
7. Such an injunction does not serve the public interest.

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To enable them to address these issues effectively at a hearing, Defendants proposed the following schedule to Pacira, which Pacira declined to accept¹ and which Defendants therefore ask the Court to order at the conclusion of the Status Conference:

Event / Task	Deadline / Date
Defendants to answer, move or otherwise respond to Plaintiff's Complaint	30 days after the Court rules on Plaintiff's Motion for Preliminary Injunction (the "PI Motion")
Defendants to serve expedited written discovery regarding PI Motion	April 30, 2021
Plaintiff to serve Objections and Responses to Defendants' expedited written discovery regarding the PI Motion	May 5, 2021
Rolling production of documents responsive to Defendants' expedited written discovery regarding the PI Motion	May 7, 2021
Plaintiff to substantially complete its production of documents responsive to Defendants' expedited written discovery regarding the PI Motion	May 19, 2021
Plaintiff to fully complete its production of documents responsive to Defendants' expedited written discovery and serve its privilege log	May 24, 2021
Defendants to complete depositions of Plaintiff's witnesses	June 14, 2021

¹ Although Pacira did not accept and intends to oppose Defendants' proposed schedule, it has agreed to give Defendants additional time to file their opposition to the motion for a preliminary injunction and thus that opposition is not due on May 3, 2021.

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Event / Task	Deadline / Date
Defendants to file their opposition to the PI Motion	June 18, 2021 (by 5:00 p.m. ET)
Plaintiff's period to depose Defendants' declarants	June 19, 2021 to July 5, 2021
Plaintiff to file its reply in further support of the PI Motion	July 8, 2021 (by 5:00 p.m. ET)
Parties to object or move to strike opposing party's evidence in support of or opposition to the PI Motion	July 13, 2021 (by 5:00 p.m. ET)
Parties to respond to objections or motions to strike evidence	July 18, 2021 (by 5:00 p.m. ET)
Hearing on Plaintiff's PI Motion	Week of July 19, 2021 (subject to the Court's availability)

Thank you for your consideration of this submission.

Respectfully submitted,



Kevin H. Marino

cc: All counsel of record